IRB Reliance Exchange
YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

STUDY MANAGER STEP-BY-STEP GUIDE

The **IREx Study Manager** is someone from the lead study team or coordinating center who uses IREx to oversee participating site readiness for single IRB (sIRB) review. For more detailed information on how to use IREx, check out the Study Manager Resources page here.

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Conversation with the Single IRB

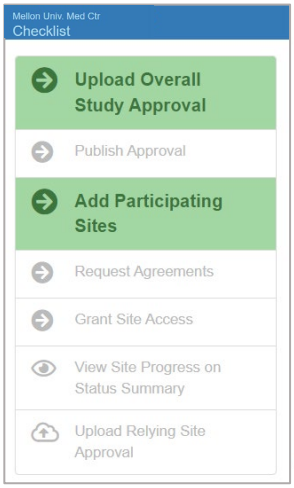
A. **Discuss** the submission process with the sIRB.
   - Review the IREx Single IRB Instructions Template for relying sites
   - Process for managing consent form (e.g., whether a template is being used)
   - Process for capturing local considerations from sites (e.g., via IREx surveys, including if the study will request local considerations updates throughout the life of the study)
   - Process for submitting sites for review (e.g., as an amendment, as a site add)

B. **Clarify** what roles you are responsible for in IREx as a Study Manger vs the sIRB. Who will:
   - Upload Initial Approval for the Overall Study/Lead Site & Publish Approval
   - Add or remove participating sites to the study
   - Request Required Agreements
   - Grant study access to participating HRPP and study teams
   - Export participating sites' reliance and local review documentation for submission to the sIRB
   - Upload Reviewing IRB Site Approvals
   - Manage study-wide amendments and continuing reviews

STEP 1 — SUBMIT THE LEAD SITE TO THE SIRB

- The **sIRB** will review the submission and create the study in IREx.
- You will receive access to IREx via an email notification after the study is created.
- While you wait for the sIRB to approve the Lead Site, you can complete steps 2 & 3.

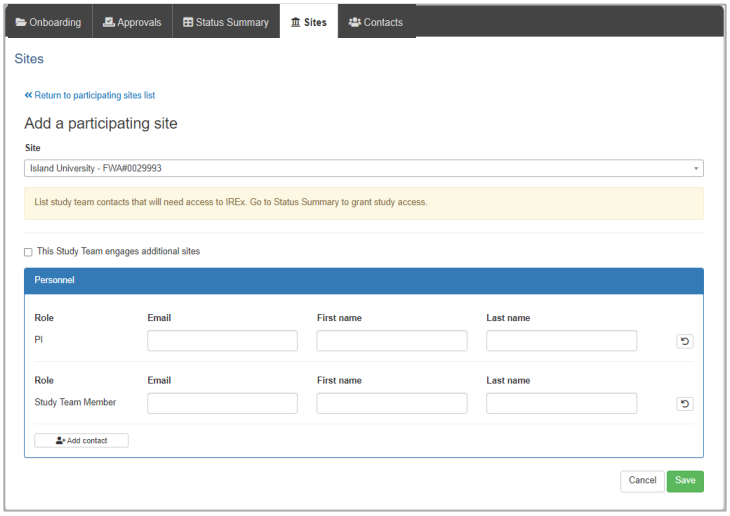
STEP 2 — ADD PARTICIPATING SITES TO THE STUDY IN IREX



A. Click **Add Participating Sites** in your Checklist, this will open your **Sites** tab.

B. Search and add site(s) by the institutions' name (avoid abbreviations, e.g. "VUMC") or by Federalwide Assurance (FWA) # (numeric characters only) or select a consortium of sites.
   - As you type, the sites that match the name/FWA # will appear. Select the site from drop-down list.
   - You can add sites that do not appear in the drop-down list by typing the site name/FWA # and pressing enter on your keyboard. An IREx admin will create the site in IREx and notify you when you can add contacts.

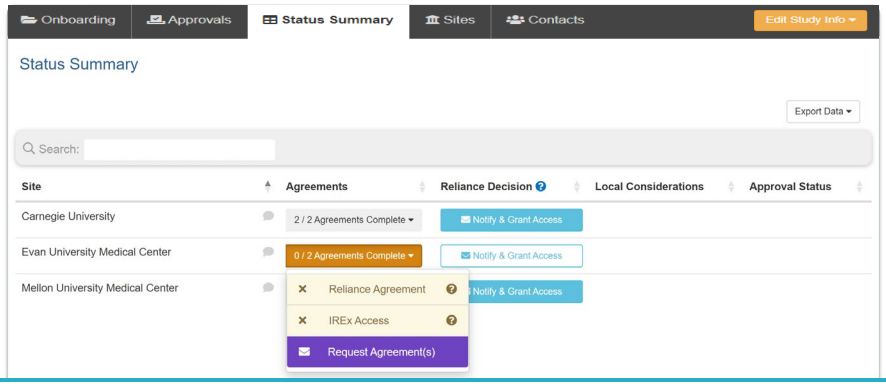
C. Enter the PI and Study Team Member contact information, if known at the time. If not, **Save** the site and return later to add this information.



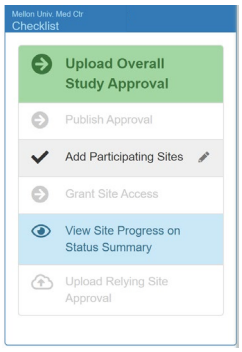
STEP 3 — REQUEST REQUIRED AGREEMENTS (IF AVAILABLE)

A. On the **Status Summary** tab, any institution that is missing agreements will have an orange number of **Agreements Complete** button with a drop-down list of agreement(s) required for the study.

B. Click the purple **Request Agreement(s)** button to send an email notification to the site.



STEP 4 — UPLOAD INITIAL SIRB APPROVAL FOR THE LEAD SITE/OVERALL STUDY & PUBLISH



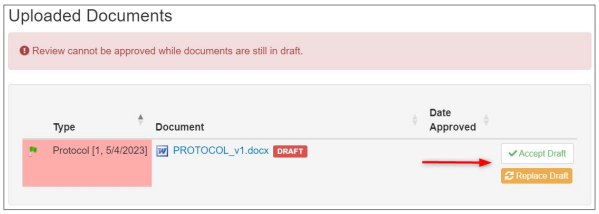
A. Click **Upload Overall Study Approval** in your Checklist. (For more detailed instructions, please view this Quick Guide.)

B. Change the Status to **Approved** and indicate the reviewing type & cycle. All required fields and documents will be highlighted in red.

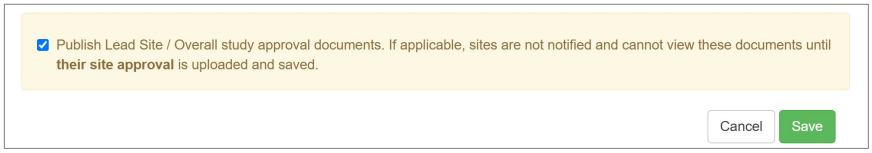
C. Enter the dates for when it was submitted, approved, review, and expires.

D. Upload your documents.

- Remember to click **Accept Draft** if the original protocol uploaded to IREx was approved or click **Replace Draft** if it was modified during the review, in which case be sure to change the version date BEFORE uploading the new file.
- Replace or accept other draft documents, as needed.

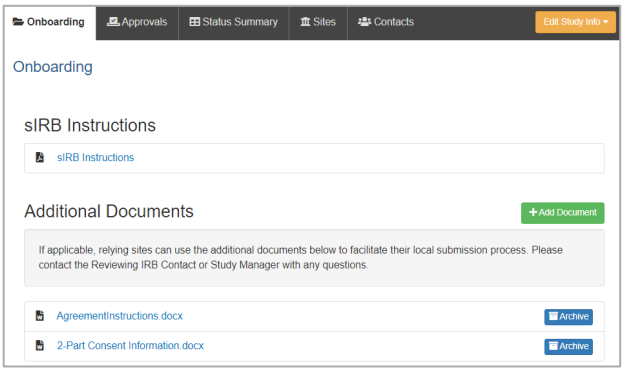


E. **Publish Approval** to make the approved global documents visible to the participating sites once they have study access. Check the box at the bottom of the Review & Submit page and click **Save.** Leave the box unselected and click **Save** if you want to return to Publish Approval later.



Step 5 — OPTIONAL: UPLOAD ADDITIONAL NON-SIRB REVIEWED DOCUMENTS TO THE ONBOARDING TAB

If you have a site specific consent template, part 2 consent template, or other document(s) to help facilitate site's local submission process, add those documents to the **Onboarding** tab. Here, sites will be able to access those documents, along with their sIRB instructions, for the life of the study. As the study moves forward, you have the ability to Archive outdated documents, and continue to add documents sites should have access to that do not go through sIRB review.

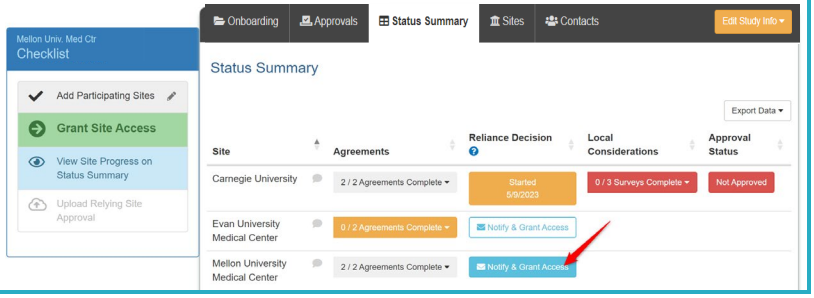


STEP 6 — NOTIFY & GRANT ACCESS TO SITES

A. Click **Grant Site Access** on your Checklist, this will open your **Status Summary** tab.

B. Click the **Notify & Grant Access** button to alert sites of their access to the study in IREx. This sends an email to the HRPP and study team to prompt them to connect around their local reliance process, gives them study access, and includes single IRB instructions for the study. The study team can use the Study Link in the email to log into IREx and download the lead site sIRB approval documents for their local submission (if applicable).

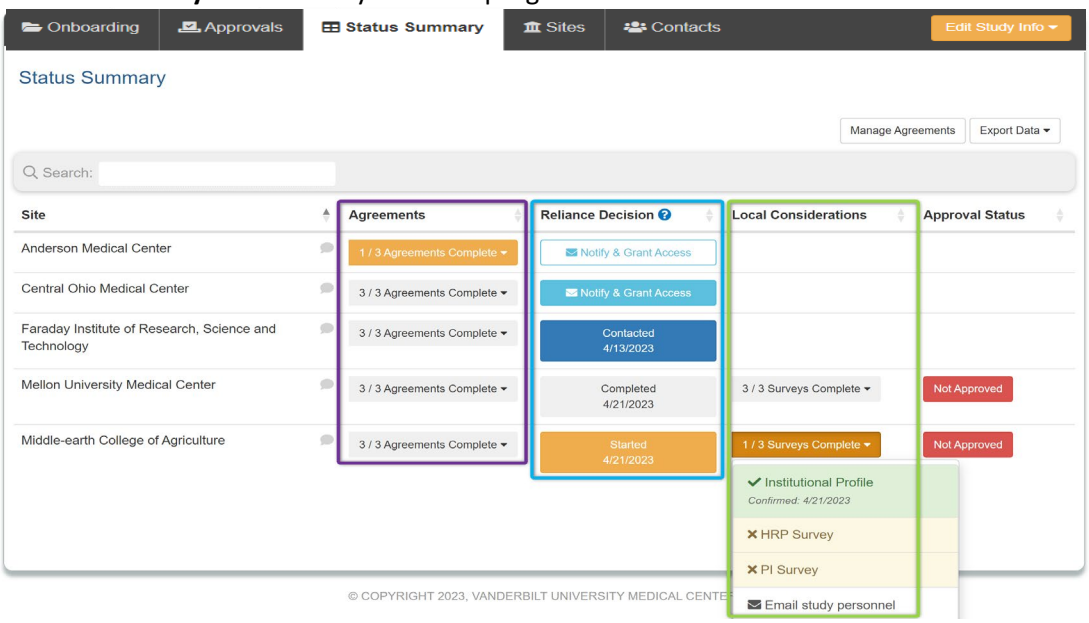
- Only sites that have joined IREx can be notified.
- You can notify sites at different times depending on when they are being onboarded to the study.



STEP 7

TRACK SITES' READINESS FOR SIRB REVIEW

Use your **Status Summary** tab to track your sites' progress.



A. Has the site signed all the required agreements?

- SMART IRB Agreement, IAA or MOU
- Indemnification (if applicable)
- IREx Access

B. Has the site's HRPP indicated reliance?

- See Reliance Decision Legend – Gray is Completed

C. Are local considerations complete?

- Institutional Profile: Completed by the HRPP; includes institution-level information.
- HRP Survey: Completed by the HRPP; includes applicable local requirements for this study.
- PI Survey: Completed by the PI or Study Team Member; includes information about the conduct of the study and an upload of the locally reviewed consent document(s). The PI must attest to the survey, as well as any edits made by a Study Team Member or the HRPP.
- CCP Summary of Results: Uploaded by PI or Study Team Member (PI attestation required). This upload is only available for Exception from Informed Consent (EFIC) studies.

Reliance Decision Legend	
Awaiting Confirmation	Reviewing IRB must accept SSRP
Add PI Info	Required PI information is not yet entered
Notify & Grant Access	Site has NOT joined IREx so cannot be granted access
Notify & Grant Access	Site has IREx access and can be notified of study access
Contacted	Site has access; click to re-send notification
Started	HRPP has accessed study in IREx
Completed	HRPP has ceded review

IREx Tip: If steps are incomplete, ensure the study team has submitted to their local IRB. If so, ask the study team to follow up with their IREx HRPP Liaison (found here) regarding steps in IREx or other requirements.

STEP 8

PRE-SCREEN AND EXPORT LOCAL CONSIDERATIONS (IF APPLICABLE)

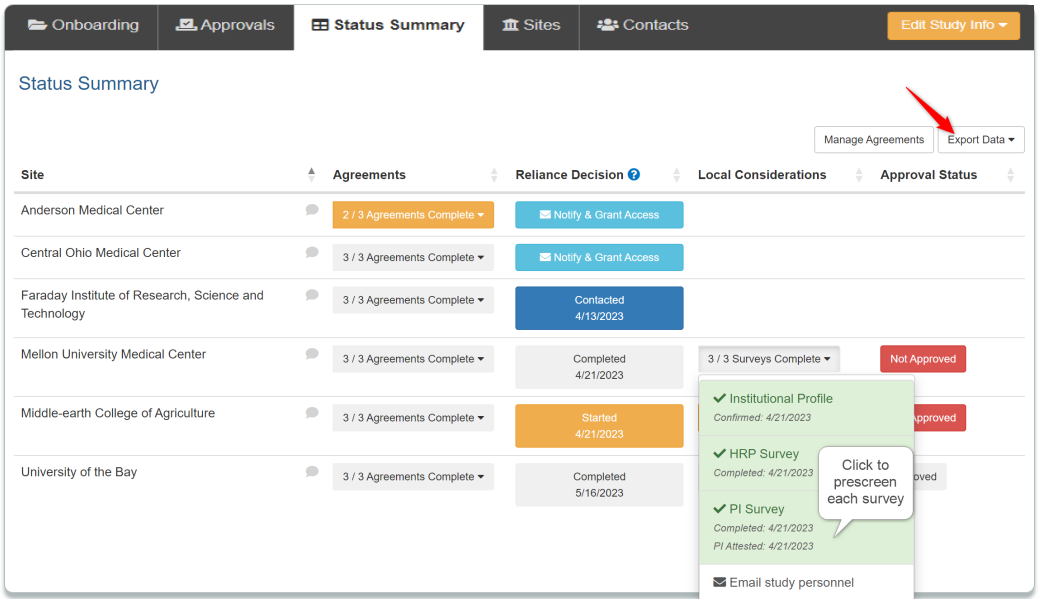
You will receive an email when sites complete local considerations. Go to the **Status Summary** tab to review.

A. **Pre-screen** the surveys for completion by clicking the 3/3 Surveys Complete dropdown to view the survey list, then click on the HRP Survey and PI Survey.

B. **Verify** consent forms are uploaded to the PI Survey, if applicable, and that they are correct. If changes or clarifications are needed, the PI and Study Team Member (or HRPP Liaison) at the site can edit the PI Survey. Only the HRPP can edit the HRP survey.

C. **Click Export Data** and select **Export Local Considerations** to download a zip file of sites' completed local considerations. Select the site(s) you need and save their files.

D. **Submit** the site's files to the sIRB for review. Contact the sIRB about submisson requirements.



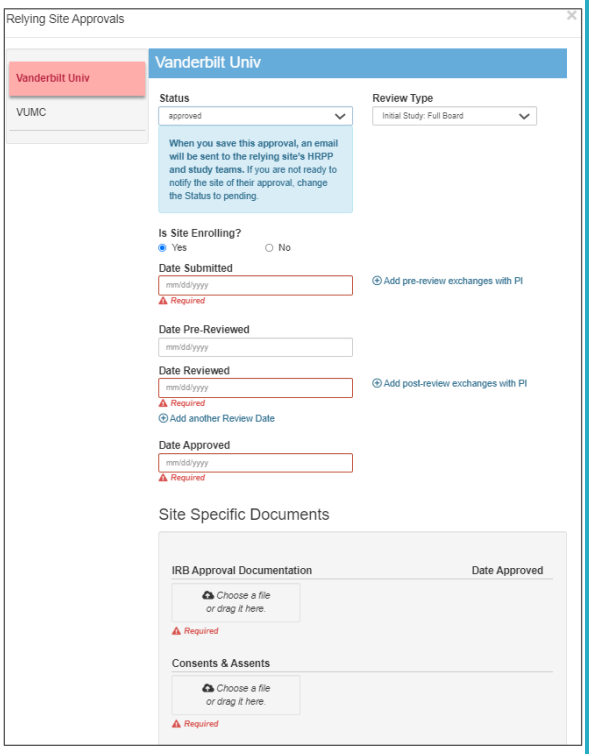
IREx Tip (EFIC Studies): Exception from Informed Consent (EFIC) studies have 4 Local Considerations surveys, rather than 3. The fourth survey is the CCP Summary of Results, which does not get uploaded by the Relying Site Study Team until the Community Consultation Plan has been implemented. Follow the steps below for EFIC studies.

1. **Documenting CCP Acceptance**
   - You will receive an email when sites complete their Institutional Profile, HRP Survey, and PI Survey (which contains an upload of the CCP for sIRB review. Follow steps A – D above to submit to the sIRB as you would for a non-EFIC study.
   - Document the sIRB's CCP acceptance by clicking **Awaiting CCP Acceptance** in the **Approval Status** column and inputting the dates of submission, review, and approval. (The accepted CCP may be uploaded; this is optional.)
2. **Submitting The CCP Summary of Results for sIRB Approval**
   - Once the study team has implemented their CPP and is ready to submit their CCP Summary of Results, they will do so via IREx, and you will receive another IREx notification. Return to the **Status Summary** tab and follow steps A – D above to submit the CCP Summary of Results to the sIRB for their review.
   - Once the CCP Summary of Results is approved and you are ready to document the Relying Site's initial approval, continue to Step 9.

STEP 9	UPLOAD INITIAL SIRB APPROVALS FOR RELYING SITES

A. Click **Upload Relying Site Approval** on your Checklist or click the **Not Approved** status for the site you wish to upload approval for on the **Status Summary** tab. (For more detailed instructions, please view this Quick Guide.)
B. **Select the site** from the list of sites on the left panel.
C. **Change** the **Status** to 'approved' and required items will turn red.
D. **Indicate** the **Review Type** (Full Board or Expedited).
E. **Is Site Enrolling?** Defaults to **Yes**, change to **No** if the site will not be enrolling participants and does not need a consent form.
F. **Enter** the Date **Submitted, Reviewed,** and **Approved**
G. **Upload** the site's **IRB Approval Documentation, Consents & Assents** (or waive), and other site-specific IRB approved documents.
H. Click **Save**.

The site HRPP and study team are notified by email when new approvals are saved, and you are cc'd.



ADDITIONAL RESOURCES

A. **Uploading other approvals** (see quick guides below)
- Continuing Review
- Study-wide Amendments
- Site Amendments

B. **Site closures -** Closing a site ensures that only active sites retain access to ongoing studies.
- Site Closure Quick Guide

C. **Study closures -** Closing a study ensures all sites are aware that the study ended but retains a record of the reliance and a history of sIRB site approvals.
- Study Closure Quick Guide